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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,106	01/30/2001	Frederick M. Ausubel	00786/362002	2344
21559	7590	02/04/2004	EXAMINER	
CLARK & ELBING LLP			TUNG, JOYCE	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	

1637

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/581,106

### Applicant(s)

AUSUBEL ET AL.

### Examiner

Joyce Tung

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10 and 12-20 is/are rejected.
- 7) ☒ Claim(s) 2-5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Based upon the response filed 9/22/2003, claims 1-10 and 12-20 are pending.

1. The rejection of claims 2-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.
2. Claims 1, 6-10 and 12-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Newton et al. (5,595,890).

Applicant's arguments filed 9/22/2003 have been fully considered but they are not persuasive. The response argues that the instant invention of claims 1 and 15 require two primers that have the same nucleotide at their 3' termini and contain at least one mismatched base and both sets of primers are capable of amplifying the same allele. Newton et al. teach a first diagnostic primer having a sequence substantially complementary to a diagnostic portion of a first nucleic acid sequence and having terminal nucleotide complementary to the suspected variant nucleotide, and a second diagnostic primer having a sequence substantially complementary to a diagnostic portion of a second nucleic acid sequence and having a terminal nucleotide complementary to the complementary suspected variant nucleotide (See column 4, lines 31-42). Although, Newton et al do not indicate that two primers amplify the same allele, based upon the teachings of Newton et al. that the second diagnostic primer has a terminal nucleotide complementary to the complementary suspected variant nucleotide (See column 4, lines 31-42), it is inherent that both diagnostic primers amplify the same allele.

The response next argues that Newton's second embodiment is directed to the use of one of two possible set of primers, one set for the variant nucleotide and one set for the normal

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nucleotide. Nevertheless, based upon the teachings of Newton et al. (See column 4, lines 31-53), the invention can be performed with two diagnostic primers as described in (a) (See column 4, lines 31-42) or (See column 4, line 42) in (b) with the second diagnostic primer having a sequence substantially complementary to the diagnostic portion of the second nucleic acid sequence and having a terminal nucleotide complementary to the normal nucleotide which corresponds to the suspected variant nucleotide (See column 4, lines 43-53). Therefore, the teachings of Newton et al. read on the limitations of the claims.

The response also argues that the listing of primers on column 6, lines 27-29 and column 29, lines 18-31 are not used to amplify the same allele in a method for determining whether a nucleic acid sequence includes a particular allele. However, the features of the primers as listed by Newton et al. meet the limitations of the features of the primer used in the instant invention.

The response further argues that Newton et al. disclose constructing a kit including the primers which have different terminal nucleotides and the two primers in the kit of claim 15 have the same terminal nucleotides. As taught by Newton et al. on column 4, lines 31-42, the two diagnostic primers would be the primers which have the same terminal nucleotides because Newton et al. do not indicate that they are different primers.

Moreover, it appears that the instant invention uses two primers, which have the same terminal nucleotide. There are no four primers used in the instant invention to form primer pair. As discussed above, the method of Newton et al. also applies two primers (See column 4, lines 31-42). Thus, based upon the analysis above, the teachings of Newton et al. anticipate the limitations of the claim. The rejection is maintained.

***Allowable Subject Matter***

3. Claims 2-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Summary**

4. No claims are allowable.

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

<sup>ST</sup>  
January 12, 2004

  
**ETHAN WHISENANT**  
**PRIMARY EXAMINER**